REMARKS

This document is submitted as a supplemental response to the final Office Action mailed July, 7, 2005 ("Office Action"). A first response to the final Office Action was filed on December 29, 2005 ("First Response"). Applicants also submit herewith a request for continued examination under 37 CFR § 1.114.

Initially, Applicants would like to thank Examiner Hayes for granting an informal interview with Applicants' counsel on January 5, 2006.

In the interview, the Examiner remarked that currently pending claim 8, drawn to a pharmaceutical preparation containing proNGF as the active ingredient, is anticipated by Edwards *et al* ("Edwards").[1] In particular, he contended that there is no structural difference between the proNGF pharmaceutical preparation recited in claim 8 and the proNGF compositions disclosed in Edwards. Moreover, he pointed out that as Edwards does not disclose a proNGF composition that, in addition to proNGF, "contains, for example, arsenic," (i.e., a highly poisonous substance), he saw no reason why any of the Edwards proNGF compositions should not be considered a proNGF pharmaceutical preparation as recited in claim 8. Applicants respectfully disagree.

It is submitted that though Edwards does not disclose a proNGF composition containing a specific poison such as arsenic, as rhetorically suggested by the Examiner, it nevertheless does disclose proNGF compositions containing crude cellular lysate components which would be deleterious if administered to a subject. See the First Response, page 6, lines 8-15. Edwards' crude proNGF compositions therefore cannot be considered pharmaceutical preparations. In contrast, claim 8 at issue covers a composition containing purified proNGF, i.e., a composition suitable for pharmaceutical use. Thus, contrary to the Examiner's position, there is indeed a patentably distinct difference between the make-up of the proNGF pharmaceutical preparation recited in claim 8 and the crude proNGF compositions disclosed by Edwards.

---

[1] Applicants note that in the First Response claim 8 was amended to recite that the proNGF in the claimed pharmaceutical preparation has activity of a level comparable to that of β NGF. As pointed out in the First Response, this amendment was made to further distinguish the proNGF pharmaceutical preparation of claim 8 from the crude proNGF compositions disclosed by Edwards, all of which had little or no activity.

In view of the remarks set forth above, Applicants submit that claim 8 is not anticipated by Edwards. For at least the same reasons, claim 20, dependent from claim 8, is also not anticipated by this reference.

Incidentally, during the interview, the Examiner noted that even if Applicants were to overcome the rejection of claims 8 and 20 based on anticipation by Edwards, he could still reject the claims as obvious over this this reference. However, Applicants wish to point out that Edwards, in fact, teaches away from using proNGF in a pharmaceutical composition. See the First Response, page 6, lines 20-27.

The Examiner also remarked that while he did not consider the claim 8 pharmaceutical preparation to be patentable over Edwards, he suggested that claims drawn to methods of preparing it might be patentable.

Accordingly, Applicants have added new claims 21-25, covering a method of preparing a proNGF pharmaceutical preparation, all of which depend from claim 8. Support for new claim 21 can be found in the Specification at page 19, line 18 through page 20, line 9. Support for new claims 22-25 can be found in the Specification, at page 14, line 13 through page 20, line 9.

It is submitted that these method claims are patentable over Edwards for at least the same reasons presented above for claim 8 and for the additional reason that Edwards does not disclose the step of renaturing denatured proNGF as recited in claim 21, from which claims 22-25 depend.[2]

[2] Applicants note that in the restriction requirement of September 9, 2004, claims drawn to methods of making β-NGF compositions were grouped separately from the elected claims drawn to a proNGF pharmaceutical preparation. It is submitted that as new claims 21-25 are drawn to methods of making the proNGF pharmaceutical preparation of claim 8, they should be entered, as they and claim 8 fall under the same general inventive concept as set forth in 37 C.F.R. § 1.475(a). Indeed, their point of patentability is the same.

CONCLUSION

Based on the remarks set forth above, Applicants submit that the pending claims cover allowable subject matter. Allowance by the Examiner is respectfully solicited.

Enclosed herewith are a request for continued examination under 37 C.F.R § 1.114 and a check for the requisite fee of $395 under 37 C.F.R § 1.17(e). Please apply any other charges to deposit account 06-1050, referencing attorney docket. 13028-002001.

Respectfully submitted,

Date: 1-9-05

Y. Rocky Tsao

Y. Rocky Tsao, Ph.D., J.D.
Attorney for Applicants
Registration No. 34,053

Fish & Richardson P.C.
Telephone: (617) 542-5070
Facsimile: (617) 542-8906
21241100.doc